MAR 1 2 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063
Phone: (650) 241-7900
Fax: (650) 241-7901

B. Contact Person

Sevrina Ciucci, RAC
Regulatory Affairs Consultant
Phone: (408) 316-4837

C. Date Prepared

December 27, 2011

D. Device Name

Trade Name:	Wildcat Catheter used with Juicebox
Common Name:	Guidewire Support Catheter and Accessory
Classification Name:	Percutaneous Catheter

E. Device Classification

Classification:	21 CFR §870.1250
Product Code:	DQY
Device Class:	Class II

F. Predicate Device

The Avinger Wildcat Catheter used with the Juicebox is substantially equivalent to the Avinger Wildcat Catheter (K111338) and the Avinger Wildcat Guidewire Support Catheter 6F used with the Juicebox (K111704).

G. Device Description

The Wildcat Catheter is a sterile, single-use, disposable catheter designed to cross chronic total occlusions (CTOs) and to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions in the peripheral vasculature.

The Wildcat Catheter consists of the distal tip, catheter shaft, and proximal handle that allows for manual device manipulation and a means for flushing the catheter lumen. The catheter is 6F guide compatible, 110 cm long, and intended for use with 0.035" guidewires. Two key elements of the device define the treatment modality – the distal tip and the bilateral wedges. Both elements are visible through fluoroscopy and allow for CTO crossing and facilitation of guidewire placement.

Subsequent to conventional guidewire placement, atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit.

Juicebox is an optional accessory used to provide assisted distal tip rotation when using a compatible Avinger catheter. It consists of a handle with a rotation toggle switch and a release button. Juicebox is designed to be placed over the catheter handle. This accessory is provided separately, irradiated for sterility, and intended for single use only.

H. Intended Use

The Wildcat Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

The Juicebox is an optional accessory that may be used to facilitate catheter tip rotation when using a compatible Avinger catheter.

I. Substantial Equivalence

The Avinger Wildcat Catheter is substantially equivalent to the Avinger Wildcat Catheter (K111338) and the Avinger Wildcat Guidewire Support Catheter 6F used with the Juicebox (K111704). The Wildcat Catheter used with the Juicebox is substantially equivalent to the stated predicates in technological characteristics, device design and packaging, procedural steps, performance testing, safety characteristics, and product labeling. The subject and predicate devices have the same mechanism of action (manual advancement of the Catheter) and perform the same function (access discrete regions of the peripheral vasculature). The Wildcat Catheter is the exact same device as the Wildcat Guidewire Support Catheter 6F and is identical in design, manufacturing, operation, and material composition as its FDA-cleared predicates, and as such, has the same technological characteristics. The changes to the Wildcat Catheter

labeling cleared under K111338 result in no significant changes to technological characteristics and do not raise any new issues of safety or effectiveness.

J. Non-Clinical Performance Data

The following non-clinical testing was conducted to support a determination of substantial equivalence to the predicate devices.

• Powered Catheter Advancement Testing
• Tip Rotation with/without Deflection Testing

The collective results of the above testing confirmed that the Wildcat Catheter performs according to the stated intended use and raises no new issues of safety or effectiveness when used with the Juicebox. Results of non-clinical testing demonstrated that the Wildcat Catheter used with the Juicebox is substantially equivalent to the predicate devices for its intended use.

K. Conclusions

The Avinger Wildcat Catheter used with the Juicebox has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Wildcat Catheter used with the Juicebox functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the Wildcat Catheter used with the Juicebox is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
c/o Ms. Sevrina Ciucci
Regulatory Affairs Consultant
400 Chesapeake Drive
Redwood, CA 94063

SEP 18 2013

Re: K113838
Trade/Device Name: Wildcat Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: December 27, 2011
Received: December 28, 2011

Dear Ms. Ciucci:

This letter corrects our substantially equivalent letter of March 12, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

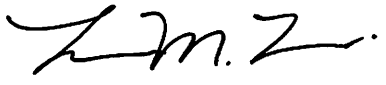
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K K113838

Device Name: Wildcat Catheter

Indications for Use:

The Wildcat Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

The Juicebox is an optional accessory that may be used to facilitate catheter tip rotation when using a compatible Avinger Wildcat catheter.

Prescription Use ___X___ **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113838